UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

SMOKING EVERYWHERE, INC.,)
Plaintiff,))
and)
SOTTERA, INC., d/b/a NJOY,)
Intervenor-Plaintiff,)
v.) Civil Case No. 09-771 (RJL)
U.S. FOOD AND DRUG ADMINISTRATION, et al.,)))
Defendants.)

ORDER

For the reasons set forth in the Memorandum Opinion, it is this <u>f</u> day of January, 2010, hereby

ORDERED that Smoking Everywhere's Motion for Temporary Restraining Order and/or Injunctive Relief [#2], which the Court has converted to a Motion for Preliminary Injunction (Minute Order dated May 1, 2009), and NJOY's Motion for Preliminary Injunction [#24] are GRANTED; it is further

ORDERED that FDA shall not detain or refuse admission into the United States of Smoking Everywhere's electronic cigarette products on the ground that those products are unapproved drugs, devices, or drug-device combinations under the Food, Drug, and

Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.; it is further

ORDERED that FDA shall not detain or refuse admission into the United States of NJOY's electronic cigarette products on the ground that those products are unapproved drugs, devices, or drug-device combinations under the FDCA, absent a proffer of evidence, consistent with the Court's Memorandum Opinion, that NJOY's products are intended to have a therapeutic effect; it is further

ORDERED that the Combined Motion for Leave to Submit a Brief Amicus

Curiae and Brief Amicus Curiae in Support of Defendant FDA by Action on Smoking

and Health [#47] and Alliance of Electronic Smokers' Motion for Leave to Participate

and File Brief as Amicus Curiae [#49] are GRANTED; and it is further

ORDERED that the Motion of Intervenor-Plaintiff Sottera, Inc. d/b/a NJOY for Leave to File Reply to Defendants' September 17th Response to Proposed Amicus [#52] and Plaintiff Smoking Everywhere, Inc.'s Motion for Leave to File Instanter a Status Report Concerning Recent Events Which May Impact Plaintiff's Continued Existence [#53] are DENIED.

SO ORDERED.

RICHARD J. LEON
United States District Judge